KENTUCKY UNDERGROUND STORAGE TANK

LABORATORY ACCREDITATION PROGRAM

REQUIREMENTS

SEPTEMBER 2005[1]

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[1] This revision updates the references to ISO/IEC 17025:2005, including renumbering and re-ordering some of the requirements. No changes have been made to the technical requirements.

KENTUCKY UNDERGROUND STORAGE TANK

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SEPTEMBER 2005

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SEPTEMBER 2005

1. Introduction

This document describes the accreditation requirements applicable to Kentucky statute KRS 224.60-130(2)(a). This statute requires the Office of the Petroleum Storage Tank Environmental Assurance Fund to establish criteria to accredit laboratories that contract with owners or operators of underground storage tanks to perform analytical testing related to Kentucky's underground storage tank program. All owners and operators shall be required to have all required analytical testing performed at an accredited laboratory to be eligible for Fund participation, pursuant to
statute 415 KAR 1:140.

This document details the requirements for accreditation and the parameters and methods on which accreditation will be granted. This requirements document will assure that laboratories performing analytical testing relating to the underground storage tank program have the technical proficiency, competency, staffing and management to properly perform analytical testing.

Internationally accepted accreditation criteria, specifically ISO/IEC 17025:2005, the A2LA Environmental Program Requirements and state requirements form the basis for accrediting laboratories under this program

Scope. A2LA will accredit environmental laboratories on an analyte specific basis. The scope of this program covers the following classes of tests: potable water, nonpotable water, and solid/hazardous waste analyses.   The program is divided into testing technologies and contaminant/analyte categories. Laboratories must be able to demonstrate that they are accredited by A2LA for compliance with one or more of the following parameters and test methods:

PARAMETER	EPA METHOD IDENTIFICATION
PAH	8100, 8310, 8270, 8270A, 8270B, 8270C
DRO	8015B
GRO	8015B
GRO/DRO	8015B
BTEX	8020A, 8020A, 8021, 8021A, 8021B
TPH (Oil and Grease)	9070, 9071, 8440
TPH (fingerprint)	8015B
TCLP Metals (8)	
Arsenic	6010, 6010A, 6010B, 6020, 7060, 7060A, 7061, 7061A, 7062
Barium	6010, 6010A, 6010B, 6020, 7080M, 7080A, 7081
Cadmium	6010, 6010A, 6010B, 7130, 7131A
Chromium	6010, 6010A, 6010B, 7190, 7191
Lead (total or dissolved)	6101, 6010A, 6010B, 7420, 7421
Mercury	6020, 7470A, 7471A, 7472
Selenium	6010, 6010A, 6010B, 6020, 7740, 7741A, 7742
Silver	6010, 6010A, 6010B, 7760A, 7760B, 7761
TCLP Volatiles (11)	8020, 8020A, 8021, 8021A, 8021B, 8240, 8260, 8260A, 8260B
TCLP Semi-volatiles	8270, 8270A, 8270B, 8270C

Assessors evaluate a laboratory for compliance with EPA-accepted methods. In addition, a laboratory must meet the minimum requirements specified in this document.

Certification Requirements

To be certified by the Office of the Petroleum Storage Tank Environmental Assurance Fund ("Office") to perform analytical testing relating to the underground storage tank program, laboratories must show current accreditation by A2LA for the "Kentucky Underground Storage Tank Laboratory Accreditation Program" (January 1999).

Application for certification shall be made to the Office of the Petroleum Storage Tank Environmental Assurance Fund on an application provided by the Office. The application shall also include proof of A2LA accreditation for the Kentucky Underground Storage Tank Laboratory Accreditation Program requirements. This proof shall consist of a congratulatory letter, signed Scope and Supplement to the Scope, and Certificate of Accreditation provided by A2LA.

Certifications issued by the Office shall be valid for two (2) years from the date of issuance by the Office. Certification may be renewed by submitting a new application and updated proof of accreditation from A2LA.

Certification may be revoked or suspended by the Office if:

(a) the applicant negligently, incompetently, recklessly, or intentionally violates any provision of these regulations and these requirements, or any state, federal, or local statute, regulation, or code or standard concerning the performance of analytical testing;

(b) the applicant obtains the certification through fraud or misrepresentation;

(c) the applicant knowingly or intentionally submits false information to owners, operators, contractors, or the Office, or

(d) the applicant loses its A2LA accreditation for one or more of the parameters and test methods specified in this requirement document (see Scope, above).

The Executive Director of the Office shall have the authority to suspend or revoke a certification. The Executive Director of the Office shall then cause a letter to be issued notifying the certified laboratory of the action.

2. General Criteria

The general criteria for accreditation are contained in ISO/IEC 17025:2005. All provisions of the general criteria shall apply under this program.

3. Specific Criteria

Specific criteria are an elaboration on or interpretation of the general criteria plus those requirements of accreditation applicable to a certain field of testing, matrix type, testing technology, type of test, or specific test. The numbering system for each section below corresponds to the requirement sections of ISO/IEC 17025. The specific criteria applicable to the Environmental Field of Testing and Kentucky Underground Storage Tank Laboratory Accreditation Program are presented in the following sections:

4. Management Requirements

4.1   Organization

(No Additions)

4.2   Quality System

(No Additions)

4.3   Document Control

(No Additions)

4.4   Review of Requests, Tenders and Contracts

(No Additions)

4.5   Subcontracting of Tests and Calibrations

(No Additions)

4.6   Purchasing Services and Supplies

(No Additions)

4.7   Service to the Client

(No Additions)

4.8   Complaints

(No Additions)

4.9   Control of Nonconforming Testing

(No Additions)

4.10   Improvement

(No Additions)

4.11   Corrective Action

4E.11.1   The laboratory shall document, investigate and take corrective action for all episodes where QC data shows an out-of-control situation. The laboratory shall keep records of all out-of-control events, the determined cause(s) and corrective actions taken. All reported data from an out-of-control event shall be appropriately qualified.

4.12   Preventive Action

(No Additions)

4.13   Control of Records

The laboratory shall establish and maintain a records system ensuring that:

4E.13.1   All observations and calculations are recorded in a permanent manner (such as laboratory notebooks, pro-forma work sheets, or magnetic media) at the time they are made and that the units of measurement in which observations are recorded are stated.

4E.13.2   Original records are uniquely identified and traceable to the test items to which they refer and to any test reports based upon them.

4E.13.3   Records are traceable, retrievable, and legible and include sufficient information and explanation such that they can be readily interpreted by staff other than those responsible for their generation.

4E.13.4   Records contain sufficient information to permit identification of possible sources of error and to permit, where feasible and necessary, satisfactory repetition of the test under the original conditions.

4E.13.5   Records contain sufficient details of any significant departures from test specifications or other specified procedures including authorizations for such departures.

4E.13.6   Records are checked for data transcription or calculation errors and the checks are documented.

4E.13.7   Records identify the person or persons responsible for their creation and the date of such creation and for the person(s) checking data transcriptions and calculations and the date of such checking.

4E.13.8   Corrections or amendments to test records are made in a manner that does not obliterate the original data and are signed or initialled and dated by the person responsible.

4E.13.9   A list of all staff documenting their initials and/or signatures as used in documents such as logbooks shall be maintained.

4E.13.10 Test records shall be protected from loss, damage, misuse or deterioration and shall be retained for an appropriate period in a manner that permits retrieval when required. Test records that are created and/or retained on magnetic media (e.g., computer disks) or photographic media (e.g., microfiche) shall be stored in a manner that protects them from the hazards that degrade such media. Provision shall be made for the printing of such records when required.

Note: Appropriate records retention periods are based upon the laboratory's various types of work, and its legal and contractual obligations.

4.14   Internal Audits

(No Additions)

4.15   Management Reviews

(No Additions)

5.   Technical Requirements

5.1   General

(No Additions)

5.2   Personnel

5E.2.1 <u>Technical Manager</u>. The technical manager (however named) shall possess a four year college degree from an accredited educational institution in chemistry or a related science or equivalent and have at least 3 years of non-academic laboratory experience. The technical manager shall be on-site at least 50% of the time.

5E.2.2 <u>Quality Manager</u>. The quality manager (however named) shall possess a four year college degree from an accredited educational institution in a basic or applied science or equivalent and have at least 1 year of non-academic laboratory experience and training in statistics. Alternatively, the quality manager can have a college degree in other than the basic or applied sciences, with at least 4 years of non-academic analytical chemistry experience and training in statistics. The technical manager may also function as the quality manager so long as he/she does not act in the position as the sample analyst/technician analyzing the samples or act as the immediate supervisor of the analyst/technician involved with the analysis of the samples. The quality manager may be employed by the laboratory on a part-time basis or as a consultant.

5E.2.3 <u>Senior Technical Staff</u>. Persons in each senior technical position shall have a bachelor's degree in a relevant scientific field or equivalent experience. At least one year of non-academic experience in relevant analysis is required. Successful training in specific methods used in the laboratory shall be verified and documented as performance evaluations using reference/control materials of the matrices of concern. Proficiency testing results must be documented.

Persons filling the following job functions must meet the associated minimum experience and training requirements:

5E.2.3.1   <u>Inductively coupled plasma-emission (ICP) spectroscopy</u>:   One year experience with satisfactory completion of a short course on ICP or an equivalent in-house training course.

5E.2.3.2   <u>Flameless atomic absorption spectroscopy</u>: One year with satisfactory completion of a short course on graphite furnace atomic absorption (GFAA) or an equivalent in-house training course.

5E.2.3.3   <u>Flame atomic absorption (FLAA) spectroscopy</u>: One year with satisfactory completion of a short course on FLAA or an equivalent in-house training course.

5E.2.3.4   <u>X-ray fluorescence (XRF) spectroscopy</u>:   One year with satisfactory completion of a short course on XRF or an equivalent in-house training course.

5E.2.3.5   <u>Gas chromatography</u>: One year with satisfactory completion of a short course on basic GC or an equivalent in-house training course.

5E.2.3.6   <u>Mass spectrometry</u>: One year with satisfactory completion of a vendor's training course, professional sponsored short course, or equivalent in-house training course.

5E.2.3.7   <u>Mass spectra interpretation</u>: One year with satisfactory completion of a vendor's training course, professional sponsored short course, or equivalent in-house training course.

5E.2.3.8   <u>General chemistry and instrumentation</u>: Six months.

5E.2.3.9 <u>Field testing</u>: Six months.

5E.2.3.10 <u>Sample collection</u>: Six months.

5E.2.4 <u>Analyst/Technician</u>. Analysts/technicians shall have completed a training course (or an equivalent in-house course) in relevant analyses and have demonstrated ability to produce reliable results through accurate analysis of reference materials (RMs), proficiency testing samples, or in-house quality control samples. Their performance must be documented. Junior staff (nondegreed personnel with less than 3 years relevant experience) must work under the direct supervision of the technical manager, or under the supervision of a senior technical person described above or under the instruction of an analyst/technician who has performed successfully over a period of three years in the relevant analyses using the same technologies being applied for the analysis of environmental samples.

5E.2.5 <u>Minimum Level of Experience Required for Independent Operation</u>.

5E.2.5.1 Sample preparation: 3 months per method used.

5E.2.5.2 Routine sample analysis: 6 months per method used.

5E.2.6 <u>Requirements during Training</u>. Analyst/technicians in training may perform work on samples submitted for environmental analysis as long as the following conditions are met:

5E.2.6.1 They have demonstrated the ability to produce reliable results through accurate analysis of RMs, proficiency testing samples or in-house quality control samples; and

5E.2.6.2 Their immediate supervisor or instructor is readily available in their work area when they are preparing and/or analyzing the samples.

5E.2.7 The laboratory shall have documented evidence contained in their training records of proficiency of all personnel for each test method or activity performed on the matrices of concern.

5.3 Accommodation and Environmental Conditions

5E.3.1 <u>Quality issues</u>. In order to prevent contamination of samples or standards, the laboratory shall:

5E.3.1.1 Use distilled/demineralized water that is demonstrated to be free of interferants at applicable detection limits.

5E.3.1.2 Check and record the conductivity of distilled/demineralized water at least once a week using a calibrated conductivity meter which is external to the water system. The point of water collection shall be from a frequently used access point.

5E.3.1.3 Exhaust hoods shall be vented in such a manner to prevent cross contamination of samples and equipment. (Example: The hood outlet of the organic extraction laboratory should not be near the air intake for the volatile organic laboratory. Evidence can be obtained by examination of laboratory blanks for contamination.)

5E.3.1.4 Provide sample storage facilities which prevent cross contamination of samples with standards, solvents, or reagents. See section 11E4 of this criteria. (Evidence of compliance may be obtained through the examination of storage areas, or through the use of laboratory storage blanks, travel/trip blanks or other blanks stored with samples.)

5E.3.2   Laboratory Safety: Each laboratory shall have a safety and chemical hygiene plan (see OSHA rule 29 CFR 1910), as part of their standard operating procedure. Where safety practices are included as part of an approved method, the practices shall be strictly followed. While more specific safety criteria are not an aspect of this accreditation program, laboratory personnel should apply general and customary safety practices as a part of good laboratory procedures. The laboratory shall:

5E.3.2.1 Have toxic chemical handling areas consisting of impervious, non-reactive material covered with absorbent material.

5E.3.2.2 Provide exhaust hoods for personnel protection (see 29 CFR 1910.1450, Occupational Exposure to Toxic Substances in Laboratories and ANSI/AIHA Z9.5-1992, Standard for Laboratory Ventilation);

5E.3.2.3 Have procedures and facilities for handling material that may transmit infectious agents (see NIH 88-8395 or equivalent);

5E.3.2.4 Store reagents, corrosives, explosives, oxidants, and flammable solvents appropriately (see OSHA rule 29 CFR 1910.1450);

5E.3.3 Waste Disposal: Each laboratory shall have waste collection, storage, and disposal procedures and policies (reference: 40 CFR 261, 262, and 264), as part of their standard operating procedures. Where disposal practices are included as part of an approved method, these practices shall be strictly followed. While more specific disposal criteria are not an aspect of this accreditation program, the laboratory should apply appropriate federal, state, and local disposal practices as a part of good laboratory procedures.

5.4   Test Methods and Method Validation

The laboratory shall:

5E.4.1 Have documented procedures for making and controlling revisions to in-house SOPs (use revised SOPs only after written authorization by senior technical personnel);

5E.4.2 Have documented procedures for data collecting and reducing, reporting and record keeping;

5E.4.3 Have documented method performance procedures to apply at appropriate levels of all measurement systems;

5E.4.4 Have documented procedures to verify test reports;

5E.4.5 Have documented procedures for correcting erroneously reported results;

5E.4.6 Prepare analytical standards at a frequency consistent with method requirements and good QC (frequency is a function of concentration and type of matrix; generally, the lower the concentration the less stable the standard);

5E.4.7 Specify the methods and do routine analyses for checking all solvents and reagents used for dilutions and extractions;

5E.4.8 SOPs for test methods shall supply or refer to information addressing the following areas:

Interferences	Instrument Calibration
Safety Considerations	Quality Control Procedures

Apparatus and Equipment	Detailed Step-by-Step Procedure
Reagents and Supplies	Sample Calculations
Sample Preservation and Storage	Method Performance Criteria
Sample Preparation	(accuracy and precision)

5E.4.9 Acceptable Methodology. Procedures published by federal agencies (e.g., USEPA, NIOSH), nationally or internationally recognized technical authorities or other validated procedures may be acceptable to use once the laboratory has demonstrated adequate performance with the method for each particular matrix. Alternative procedures and/or modifications of methods may be used if they have been EPA or State approved.

5E.4.10 Calibration range. Linear calibration ranges (or working calibration ranges) shall be established and routinely verified for each method.

5E.4.11 Method detection limits. Method detection limits (MDLs) shall be established and statistically verified at least annually where appropriate for each method and matrix of concern.

5E.4.11.1 For methods with stated MDLs, the laboratory shall demonstrate and document its ability to achieve such MDLs.

5E.4.11.2 MDLs shall be determined using procedures published or recognized by USEPA. An example of an acceptable recommended procedure is in 40 CFR Part 136, Appendix B.

5.5 Equipment

For analytical balances/pan balances:

5E.5.1 Analytical balances shall be capable of weighing to 0.1 mg.

5E.5.2 Records of balance calibration shall be kept covering at least the effective range of its use traceable to Class 2 or 3 (per ASTM E617) reference weights (formerly classified as Class S and S-1).

5E.5.3 Records showing functional/calibration checks for each day of use for analytical balances and monthly for pan balances shall be maintained. (Note: Criteria for the accuracy of balances must be established. ASTM E200-91 recommends an accuracy of 0.1% or less.)

5E.5.4 The balances shall be serviced and calibrated at least annually by an authorized person and a certificate shall be provided and retained identifying traceability to an appropriate national/international measurement standards body, such as the National Institute of Standards and Technology (NIST).

5E.5.5 The reference weights shall be calibrated at least every five years.

For pH meters:

5E.5.6 The laboratory shall use a clean pH meter with appropriate electrode with scale graduations at least 0.1 pH units (calibrated to $\pm$ 0.1 pH units for each use period).

5E.5.7 Either a thermometer or a sensor for temperature measurement to make corrections for pH measurement or an automatic compensation device shall be in use.

5E.5.8 Either a magnetic, TFE-coated stirring bar or a mechanical bar with inert plastic-coated impeller shall be available.

5E.5.9 Records shall be kept showing daily, or before each use, calibration, whichever is less frequent. Calibration shall be performed with at least two buffers in the pH range expected in the samples.

5E.5.10   Aliquots of standard pH 4 & pH 7, or pH 7 & pH 10 shall be used only once.

For conductivity meter:

5E.5.11   A conductivity meter with an error not exceeding 1% or 1 μmhos/cm, whichever is greater, shall be in use.

5E.5.12   Records shall be kept to show a daily, or before each use, calibration check, whichever is less frequent.

5E.5.13   Records shall be kept showing that the cell constant is determined annually.

For glassware:

5E.5.14   Glassware shall be cleaned in a manner appropriate for the analytical procedures for which it is used including protocols for: metals, ammonia, phosphorus, volatiles and semivolatiles. These cleaning procedures shall be documented.

For refrigerators:

5E.5.15   The bulb of the thermometer in each refrigerator shall be immersed in liquid.

5E.5.16   Thermometers shall be graduated in increments no larger than $1^{o}C$.

5E.5.17   Records shall be kept to show that refrigerator temperatures are maintained in the range of 2 - $5^{o}C \pm 1^{o}C$.

5E.5.18   Samples to be analyzed for volatile organic compounds (VOCs) shall be stored in separate refrigerators from all other samples.

For ovens:

5E.5.19   Thermometers shall be graduated in increments no larger than $1^{o}C$.

5E.5.20   If oven temperature cannot be read without opening the door, the bulb of the thermometer shall be immersed in a sand bath. (A second thermometer should be used to evaluate hysteresis of operation.)

5E.5.21   Oven temperatures shall be controlled and monitored (e.g., beginning and end of each use cycle) to meet applicable method requirements.

For microwave ovens:

5E.5.22   The calibration of the power available for heating shall be documented at least weekly in order to determine that the microwave has not started to degrade and that absolute power settings (watts) may be compared from one microwave to another. (EPA 600/8-91/213; NTIS PB92-114172)

For hot plates:

5E.5.23   Monitor temperature at the center of the hot plate where appropriate and document results. (Note: An uncovered beaker containing 50 ml of a liquid such as an oil located in the center of the hot plate can be used to estimate the temperature.)

For incubators/water baths:

5E.5.24   Method specific temperature requirements shall be controlled and monitored during the course of a test and appropriate records maintained to assure compliance.

For thermometers:

5E.5.25   The laboratory shall have access to a NIST-traceable thermometer

5E.5.26   The calibration (correction factors) of working liquid-in-glass thermometers shall be checked at least annually against a NIST-traceable certified thermometer.

5E.5.27   The calibration (correction factors) of dial-type thermometers shall be checked at least quarterly against a NIST-traceable thermometer.

5E.5.28   The NIST-traceable thermometer(s) shall be calibrated at least every five years.

For autopipetors/dilutors:

5E.5.29   Apparatus having sufficient sensitivity for the application shall be in use.

5E.5.30   Records shall be kept showing delivery volumes are checked gravimetrically as appropriate each month of use.

5.6   Measurement Traceability

The laboratory shall:

5E.6.1 Use quality control materials and calibration standards that are traceable to appropriate national/international measurement standards, where available;

5E.6.2 Document the frequency, conditions, and standards used to establish calibration of all analytical/testing methodology;

5E.6.3 Verify and document all working standards versus primary (reference) standards where available;

5E.6.4 Document the traceability of the specific calibration, calibration check, control, or reference standards, samples, or mixtures of such standards or samples used to establish or verify the validity of the analytical measurement;

5E.6.5 Label reference materials/reagents with concentrations, date of preparation, expiration date and the identity of the person preparing the reagent;

5E.6.6 Refrain from using any material beyond the specified expiration date unless documented procedures have been followed for assigning a revised expiration date; and

5E.6.7 Have standards preparation documentation such as a preparations record book.

5E.6.8 Instrument performance checks shall be carried out before use for analysis of samples. Such

checks shall include, as appropriate, evaluation of instrument sensitivity, noise levels and absorbance/emission levels versus historical values. Acceptance criteria shall be stated.

5E.6.9 Standard curves shall be prepared to adequately cover the expected concentration ranges of the samples using a minimum of 3 data points for each analyte and one blank, unless otherwise specified by the method employed. Acceptance criteria shall be stated. If acceptance criteria are not met, the problem must be resolved before generating reportable data.

5E.6.10 Field testing devices shall be calibrated as required by the testing procedure. Acceptance criteria shall be stated. In the absence of a requirement in the testing procedure, calibration shall be in accordance with the manufacturer's specification. Calibration records shall be maintained.

5.7   Sampling

(No Additions)

5.8   Handling of Test Items

The laboratory shall:

5E.8.1 Have adequate written procedures for receipt, storage and processing of samples (including as applicable trip and field blanks) to ensure that holding times are met;

5E.8.2 Give samples an unambiguous sample identification when logged.

5E.8.3 Maintain a permanent record for sample log-in data.

5E.8.4 Store samples in such a way as to maintain their identity, integrity, stability, and concentration.

5E.8.5 Maintain sample preservation records.

5E.8.6 Follow appropriate documented chain-of-custody procedures, when required.

5E.8.7 Document failure of sample collector to use appropriate containers, preservatives, packaging, and incorrect documentation and labeling upon receipt of samples.

5E.8.8 Samples disposal must meet waste disposal criteria as applicable.

5.9   Assuring the Quality of Results

5E.9.1 Quality Control (QC) Procedures. The laboratory shall comply with the quality control (QC) procedures required by applicable federal or state environmental or public health agencies when testing for specific analytes. The laboratory shall have QC procedures (SOPs) specific to each test technology addressing, as appropriate, the use of:

5E.9.1.1   Reagent/method blank analyses;

5E.9.1.2   Trip blanks and field blanks;

5E.9.1.3   Replicate/duplicate analyses;

5E.9.1.4   Spiked sample analysis;

5E.9.1.5   Blind samples;

5E.9.1.6   Surrogate standards;

5E.9.1.7   Laboratory control samples (LCSs);

5E.9.1.8   Control charts or the equivalent (e.g., quality control database);

5E.9.1.9   Calibration standards, blanks, and calibration devices (e.g., electronic conductivity meter, NIST-traceable thermometer);

5E.9.1.10 Reference material samples; and

5E.9.1.11 Internal standards.

5E.9.2 <u>Quality Control Practices</u>.

5E.9.2.1   The laboratory shall continually evaluate its performance (system process control) for each method and matrix which includes the determination of accuracy and precision.

5E.9.2.2   Supervisory personnel shall conduct a documented review of the data calculations and QC results.

5E.9.2.3   Deviations or deficiencies in QC shall be reported to management, and such reports shall be documented. QC data shall be retrievable for all analytical results.

5E.9.2.4   Method detection limits (MDLs) shall be determined and documented.

Note: Confirmation of MDLs shall be done as appropriate or as required by the method.

5E.9.3 <u>Acceptance Limits</u>. Acceptable performance limits for analytical instrumentation as well as each method shall be documented based upon the continuing statistical evaluation of data generated by the analysis of quality control samples, unless specific minimum acceptance limits are established by the method.

5E.9.4 Where applicable, the following minimum QC shall be practiced in the laboratory:

For Inorganics/ Classical Chemistry:

5E.9.4.1   One calibration check standard and associated blank in 20 samples tested; the lab should repeat analysis of all affected samples if the calibration check standard is outside $\pm$ 10% of expected value unless the method specifies otherwise (Broader acceptance ranges must be fully justified and documented).

5E.9.4.2   One reagent, method, or digestion blank (carried through preparation) in 20 (or per batch).

5E.9.4.3   One matrix spike in 20 (or per batch).

5E.9.4.4   One duplicate or matrix spiked duplicate in 20 (or per batch).

5E.9.4.5   One laboratory control sample in 20 (or per batch).

Note 1: Analysis of a low concentration or near MDL (2 to 3 times MDL) standard with each batch of 20 samples or less is recommended to assess analytical system performance near the MDL (required in CLP SOWs for metals when client needs results near MDL).

Note 2: A batch includes up to 20 samples plus the attendant QC samples unless otherwise specified.

       For Organics:

5E.9.4.6 One calibration check standard in 20 samples (or method-specific frequency) inside established control limits; if any are outside the limits, repeat analysis of all affected samples.

5E.9.4.7 One reagent, method or preparation blank (carried through preparation) in 20 (or per batch).

5E.9.4.8 One matrix spike in 20 (or per batch).

5E.9.4.9 One duplicate or matrix spike duplicate in 20 (or per batch).

5E.9.4.10 Internal or external standards and surrogates (where available) shall be used for all samples.

5E.9.4.11 As required by the method, one laboratory control sample (consists of a representative matrix spiked with a reference standard containing the target analytes) in 20 (or per batch).

Note: Analysis of a spiked blank water or soil (LCS)(sodium sulfate or silica sand for organics) which is subjected to ALL extractions and cleanups with each batch of 20 samples or less is recommended to evaluate analytical system performance (CLP Statement of Work (SOW) requires analysis of an LCS).

5E.9.5 The laboratory shall establish control limits for all the above types of QC samples and be able to explain and document the basis for such established limits

5E.9.6 Control Charts. Control charts or control data shall be used to track laboratory performance with the associated acceptance limits for each matrix and to evaluate instrument performance.

5.10   Reporting the Results

(No Additions)

PROFICIENCY TESTING (PERFORMANCE EVALUATION) REQUIREMENTS

Please refer to the A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories.

APPENDIX A

ACRONYMS AND GLOSSARY OF TERMS ASSOCIATED WITH THE PROGRAM

ACRONYMS

AA   Atomic Absorption or Automated Analysis (wet chemical)
AAS   Atomic Absorption Spectrometry (see FLAA and GFAA)
A2LA   American Association for Laboratory Accreditation
AIHA   American Industrial Hygiene Association
ANSI   American National Standards Institute
AOAC   Int.Association of Official Analytical Chemists International
APHA   American Public Health Association
ASTM   American Society for Testing and Materials
ASTPHLD   Association of State and Territorial Public Health Laboratory Directors
AWWA   American Water Works Association
C   Celsius (temperature unit)
CCB   Continuing Calibration Blank
CCV   Continuing Calibration Verification
CERCLA   Comprehensive Environmental Response, Compensation & Liability Act
CDC   Centers for Disease Control
CFR   Code of Federal Regulations
CNAEL   Committee on National Accreditation of Environmental Laboratories
CRADA   Cooperative Research and Development Agreement
CLP   Contract Laboratory Program
CRM   Certified Reference Material
EDL   Estimated Detection Limit
ELPAT   Environmental Lead Proficiency Analytical Testing (AIHA/NIOSH)
EMPC   Estimated Maximum (Possible) Concentration used for dioxin and furans analyses
EPA   Environmental Protection Agency (see also USEPA)
EQL   Estimated Quantitation Limit
FIFRA   Federal Insecticide, Fungicide and Rodenticide Act
FLAA   Direct Flame Aspiration Atomic Absorption Spectrometry
GFAA   Graphite Furnace Atomic Absorption Spectrometry
GLP   Good Laboratory Practices (TSCA and FIFRA)
HPLC   High Performance Liquid Chromatography
IC   Ion Chromatography
ICB   Initial Calibration Blank
ICP-AES   Inductively Coupled Plasma Atomic Emission Spectrometry
ICP/MS   Inductively Coupled Plasma-Mass Spectrometry
ICV   Initial Calibration Verification
ICS   Interference Check Standard
IDL   Instrument Detection Limit
IEC   International Electrotechnical Commission
IMVL   Interlaboratory Method Validation Study
ISO   International Organization for Standardization
LCS   Laboratory Control Sample
LOQ   Limit of Quantitation
LSA   Laboratory Systems Audit
MBAS   Methylene Blue Active Substances
MCL   Maximum Contaminant Level
MDL   Method Detection Limit
MOU   Memorandum of Understanding
NIOSH   National Institute for Occupational Safety and Health

NIST   National Institute of Standards and Technology
NLLAP   National Lead Laboratory Accreditation Program
NTIS   National Technical Information Service
OSW   Office of Solid Waste (USEPA)
PCBs   Polychlorinated biphenyls
PE   Performance Evaluation
PM   Preventive Maintenance
PT   Proficiency Testing
PQL   Practical Quantitation Limit
QA   Quality Assurance
QAMS   Quality Assurance Management Staff
QAPjP   Quality Assurance Project Plan
QAPP   Quality Assurance Program Plan
QC   Quality Control
QM   Quality Manual
RCRA   Resource Conservation and Recovery Act
RE   Relative Error
RPD   Relative Percent Difference
SAP   Sampling and Analysis Plan
SARA   Superfund Amendments and Re-authorizations Act of 1986
SM   Standard Methods for the Examination of Water and Wastewater
SOP   Standard Operating Procedure
SRM   Standard Reference Material (produced by NIST)
SW   Solid Waste (usually as part of SW846, an EPA RCRA methods document)
TCLP   Toxicity Characteristic Leaching Procedure
TFE   Tetraflouroethylene (Teflon or equivalent)
TOC   Total Organic Carbon
TOX   Total Organic Halides
TQM   Total Quality Management
TSCA   Toxic Substances Control Act
USEPA   United States Environmental Protection Agency (see also EPA)
WP   Water Pollution
WS   Water Supply
XRF   X-Ray Fluorescence

GLOSSARY

Accreditation: A formal recognition that an organization (e.g., laboratory) is competent to carry out specific tasks (e.g., tests) or specific types of tasks. See also Certification.

Acceptance limits: Data quality limits specified for analytical method performance.

Accuracy: The closeness of agreement between a test result and an accepted reference value. The term accuracy, when applied to a set of observed values, will be a combination of a random component and of a common systematic error or bias component. Since in routine use, random components and bias components cannot be completely separated, the reported "accuracy" must be interpreted as a combination of these two components. See Precision and Bias.

Aliquot: See Subsample

Assessment: The process of obtaining information on an entity to evaluate its conformance or non-conformance with specified criteria. An assessment generally includes or is intended to mean an on-site visit of the entity.

Assessor: An individual who carries out some or all functions related to laboratory assessment (auditor is a common synonym).

Batch: A quantity of material produced or processed in one operation, considered to be a uniform, discrete unit.

Bias: The difference between the population mean of the test results and an accepted reference value. Bias is a systematic error as contrasted with a random error. There may be one or more systematic error components contributing to the bias.

Blank, Analytical: See Blank, Digestion.

Blank, Calibration: See Blank, Initial Calibration and Blank, Continuing Calibration blank.

Blank, Continuing calibration (CCB): A standard solution which contains no analyte and is used to verify blank response and freedom from carryover, analyzed after the CCV and after the Interference Check Standard (ICS).

Blank, Digestion: See Blank, Method.

Blank, Method: A mixture of all reagents used for the extraction or digestion of the matrix to evaluate the process for contamination from the laboratory. This blank will be run through the entire method.

Blank, Field: A sample of media carried to the sampling site, exposed to the sampling conditions (e.g., bottle caps removed), returned to the laboratory, treated as an environmental sample, and carried through all steps of the analysis in order to evaluate possible site contamination sources such as airborne contaminants.

Blank, Laboratory: See Blank, Method.

Blank, Matrix: A sample of the matrix without the analytes of interest that goes through the complete analysis including digestion.

Blank, Initial calibration (ICB): A standard solution that contains no analyte and is used for initial calibration and zeroing instrument response.

Blank, Reagent: See Blank, Method.

Blank, Rinseate: A sample of a "used" cleaning fluid rinse solution, also called an equipment blank (e.g., a final rinse of the device used to collect environmental samples) used in rinsing collection media and equipment prior to use to monitor possible cross contamination.

Blank, Spiked Reagent: A specified amount of Reagent Blank fortified with a known mass of the target analyte(s), usually to determine the recovery efficiency of the method.

Blank, Trip: A sample of media taken from the laboratory to the sampling site and returned to the laboratory unopened, to evaluate the integrity of the sample container and its preparation.

Blind sample: A subsample submitted for analysis with a composition and identity known to the submitter but unknown to the analyst and used to test the analyst's or laboratory's proficiency in the execution of the measurement process.

Calibrate: To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the calibration standards should bracket the range of planned measurements. See Calibration curve.

Calibration-check: See Calibration verification.

Calibration-check
standard: See Calibration verification.

Calibration curve: The graphical relationship between the known values for a series of calibration standards and instrument responses.

Calibration drift: The difference between the instrument response and a reference value after a period of operation without recalibration. See Continuing calibration verification.

Calibration
 standard: A substance or reference material used to calibrate an instrument (often called a calibrant).

Calibration
 solution: See Calibration standard.

Calibration
 verification: See Initial or continuing calibration verification.

Certification: A procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements. See also Accreditation.

Certified Reference   A reference material that has one or more of its property values established
 Material (CRM):   by a technically valid procedure and is accompanied by or traceable to a certificate or other documentation issued by a certifying body. See Certification and Reference material.

Chain of custody: An unbroken trail of accountability that ensures the physical security of samples, data, and records.

Check sample: An uncontaminated sample matrix spiked with known amounts of analytes, usually from the same source as the calibration standards, to establish the stability of the analytical system or to assess the performance of all or a portion of the measurement system. See also Quality control sample.

Continuing calibration
verification (CCV): A standard solution (or set of solutions) used to verify freedom of excessive instrumental drift with the concentration near mid-range of linear curve.

Control chart: A graph of some measurements plotted over time or sequence of sampling, together with control limit(s) and, usually, a central line and warning limit(s).

Control sample: See Laboratory control sample.

Corrective action: Action taken to correct a deficiency noted in an assessment. See Deficiency and Assessment.

Deficiency: A failure to comply with one of the requirements of the program usually noted during an assessment. See Assessment.

Duplicate analyses: The analyses or measurements of the variable of interest performed identically on duplicate samples.

Duplicate samples: Two samples taken from and representative of the same population and independently carried through all steps of the sampling and analytical procedures in an identical manner. Laboratory duplicates are used to assess variance of sub-sampling and analysis. Field duplicate samples are used to assess variance of the total method including sampling and analysis.

Field sample: A sample collected and delivered to the laboratory for analysis.

Initial calibration
verification (ICV): A standard solution (or set of solutions) used to verify calibration standard levels whose concentration of analyte is near mid-range of linear curve and is made from a stock solution having a different manufacturer or manufacturer lot identification than the calibration standards.

Instrument
maintenance log: A chronological record of preventive and emergency maintenance performed on an analytical instrument. The logs include record of calls, service technician summaries, records of calibration etc.

Interference check
standard (ICS): A standard solution (or set of solutions) used to verify accurate analyte response in the presence of possible interferences from other analytes present in samples.

Internal standard: A standard added to a test portion of a sample in a known amount and carried through the entire demonstration procedure as a reference for calibration and controlling the precision and bias of the applied analytical method.

Intralaboratory
precision: A measure of the method/sample specific analytical variation within a laboratory, usually given as the standard deviation estimated from the results of duplicate analyses.

Laboratory control
sample (LCS): A reference material with an established concentration obtained from a source independent of the instrument calibration and traceable to an appropriate national/international measurement standard or other certified reference material.

Laboratory sample: An aliqout or sub-sample of a field sample upon which laboratory analyses are made and results gathered.

Lot: A set of samples submitted together for laboratory analysis which can be treated as one or more batches.

Matrix: The component or substrate which contains the analyte(s) of interest.

Matrix spike: An aliquot of sample spiked with a known concentration of target analyte(s) prior to sample preparation and analysis in order to document the bias of a method in a given sample matrix.

Matrix spike
 duplicate: Intralaboratory split samples spiked with identical concentrations of target analyte(s) prior to sample preparation and analysis in order to document the precision and bias of the method in a given sample matrix.

Method performance: A general term used to document the characteristics of a method. These characteristics usually include method detection limits, linearity, precision, accuracy and bias.

Method detection The minimum concentration of an analyte that, in a given
 limit (MDL): matrix and with a specific method, can be identified, measured and reported with 99% confidence that the analyte concentration is greater than zero.

Mobile laboratory: A mobile laboratory is a self-contained, mobile facility that moves under its own power or is conveyed on a trailer, and does not remain at a site for more than two years.

NLLAP requirements: Requirements specified by the EPA National Lead Laboratory Accreditation Program (NLLAP) in order to be accredited for lead analysis in paint, soil and dust matrices by an EPA-recognized laboratory accreditation organization such as A2LA.

Precision: The closeness of agreement between test results obtained under prescribed conditions. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

Primary standard: A substance or device with a property or value that is unquestionably accepted (within specified limits) in establishing the value of the same or related property of another substance or device.

Proficiency testing: Methods of checking laboratory testing performance by means of interlaboratory tests.

Quality assurance
 (QA): For laboratories, the activity of providing the evidence needed to establish confidence that laboratory data are of the requisite accuracy.

Quality control
 (QC): For laboratories, the process through which a laboratory measures its performance, compares its performance with standards and acts on any differences.

Quality system: For laboratories, the organization structure, responsibilities, procedures, processes and resources needed to ensure that laboratory services satisfy data requirements.

Quantitation Limits: The maximum or minimum levels or quantities of a target analyte that can be quantified with the certainty required by the data user.

Reference material: A material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or assigning values to materials.

Reference standard: See Reference material.

Relative percent
difference: A term defined as:

$$RPD = \frac{|R_1 - R_2|}{\overline{R}} \times 100$$

where | R₁ - R₂ | represents the absolute difference in two values andR represents the average of the two values.

Replicate analyses: The analysis of the quantity (or analyte) of interest performed identically on two or more laboratory subsamples of the same field sample within a short time interval.

Run: A set of consecutive sample measurements.

Sample log: The document where sample identification, condition, etc is noted when samples arrive at the laboratory. The log is part of the sample tracking system. See Sample tracking.

Sample tracking: A system of following a sample from receipt at the laboratory, through sample processing and analysis, and to final reporting. The system includes unique numbering or bar coding labels and the use of a sample log.

Secondary standard: A standard whose value is based upon comparison with a primary standard.

Site blank: See Field blank.

Spiked matrix: See Spiked sample.

Spiked sample: A sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available, used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Split samples: Two or more representative portions taken from a sample or subsample and analyzed by different analysts or laboratories used to replicate the measurement of the variable(s) of interest.

Standard addition: The procedure of adding known increments of the analyte of interest to a sample to cause increases in detection response to subsequently establish by extrapolation of the plotted responses the level of the analyte of interest present in the original sample.

Standard operating
procedure (SOP):A written document that details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing a certain routine or repetitive task.

Standard reference
material (SRM): A certified reference material produced by the U.S. National Institute of Standards and Technology and characterized for absolute content independent of analytical method.

Stock solution: A concentrated solution of analyte(s) or reagent(s) prepared and verified by prescribed procedure(s), and used for preparing working standards or standard solutions.

Stratification: The division of a target population into subsets or strata which are internally more homogeneous with respect to the characteristic to be studied than the population as a whole.

Subsample: A representative portion of a sample. A subsample may be taken from any laboratory or a field sample.

Surrogate: An organic compound which is similar to the target analyte(s) in chemical composition and behavior in the analytical process, but which is not normally found in environmental samples.

Validation: The process of substantiating specified performance criteria.

Working standard: See Secondary standard

Document Revision History

Date	Description
June 29, 2001	General Criteria updated to reference ISO/IEC 17025. Specific Criteria numbering and order changed to match ISO/IEC 17025. Document Revision History section added. No other changes made.
September 13, 2005	Updated to reference ISO 17025: 2005